AUG 3 0 2000

K00 1946

GE Medical Systems

P.O. Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

° This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

° Identification of Submitter
Larry A. Kroger, Ph.D., 262-544-3894, July 16, 2000

° Identification of the Product
Signa Profile Neurovascular Array Coil

Manufacturer Address: GE Yokogawa Medical Systems, Ltd.
4-7-127, Asahigaoka, Hino-shi
Tokyo, 191-8503 Japan

° Marketed Devices
The Signa Profile MR System with the Neurovascular Array Coil is substantially equivalent to the currently marketed Signa Profile Head Coil and the MRI Devices Corporation Neurovascular Array Coil.

° Device Description
The Signa Profile Neurovascular Array Coil is a receive only coil. It is designed for use with a vertical magnetic field MR imaging system.

° Indications for Use
It is intended to be used to image the Brain, Brain Angiography, Cervical Spine, Neck and Neck Angiography.

° Comparison with Predicate
The Signa Profile Neurovascular Array Coil is similar in construction to currently marketed Signa Profile Head Coil and the MRI Devices Corporation Neurovascular Array Coil. Except that the Signa Profile Neurovascular Array Coil has a bigger coverage and uses phased array technology. The array is designed for high productivity imaging of the brain and neck regions.

° Summary of Studies
The Signa Profile Neurovascular Array Coil was evaluated to the appropriate NEMA performance standards MS#6 for Special Purpose Coils as well as the IEC 601-1 International medical equipment safety standard. The Coil is comparable to the predicate devices.

° Conclusions
It is the opinion of GE that the Signa Profile Neurovascular Array Coil is substantially equivalent to the Signa Profile Head Coil and the MRI Devices Corporation Neurovascular Array Coil. The use of this Coil does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201

Re: K001946
Signa Profile Neurovascular Array Coil
Dated: June 16, 2000
Received: June 26, 2000
Regulatory Class: II
21 CFR §892.1000/Procode: 90 MOS

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(K) Number (if known): K00 1946

Device Name: Signa Profile Neurovascular Array Coil

Indications For Use:

The Indications for Use for the Signa Neurovascular Array Coil expands the imaging performance of the Signa Profile System.

The Neurovascular Array Coil can be used to image the following regions of anatomy:

- Brain
- Brain Angiography
- Cervical Spine
- Neck
- Neck Angiography

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, **Abdominal, ENT,**
and Radiological Devices
510(k) Number K001946

Prescription Use ✓ OR Over – The – Counter Use _____
(Per 21 CFR 801.109)